

GP-2881

Docket No.: CI-0003

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Shirley I. MIEKKA et al.

Serial No.: 09/942,941

Group Art Unit: 2881

Filed: August 31, 2001

Examiner: Unassigned

For: METHODS FOR STERILIZING
PREPARATIONS CONTAINING
ALBUMINSUPPLEMENTAL INFORMATION DISCLOSURE STATEMENTAssistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. One copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the indicated date. Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, that information cited in the statement is considered to be and/or is material to patentability, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that was cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. §120. 1138 OG 37, 38 (May 19, 1992).

- X 1. This Information Disclosure Statement is being filed (i) within three months of the U.S. filing date of a U.S. application other than a CPA continued prosecution application under §1.53(d) OR (ii) within three months of the date of entry of the national stage as set forth in §1.491 in an international application OR (iii) before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 C.F.R. §1.97(b).
- 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application. 37 C.F.R. §1.97(c).
- a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).

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- b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).
 - c. Attached is our check no. _____ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.
 - 3. This Information Disclosure Statement is being filed after the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application, but on or before payment of the Issue Fee. Attached is our check no. ____ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 C.F.R. §1.97(d).
 - a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).
 - b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).
- X 4. The relevancy of the non-English language references can be determined from the attached abstracts.

X 5. To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,
FLESHNER & KIM, LLP

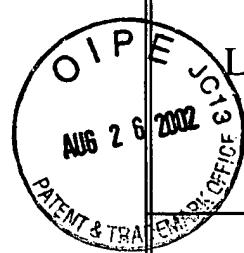


Mark L. Fleshner
Registration No. 34,596
Donald R. McPhail
Registration No. 35,811

Correspondence Address:

P.O. Box 221200
Chantilly, VA 20153-1200
Telephone: (703) 502-9440
Date: **August 26, 2002**

MLF/DRM:dbp



**LIST OF PRIOR ART CITED BY
APPLICANT
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ATTY. DOCKET NO.
CI-0003APPLN. SERIAL NO.
09/942,941APPLICANT
Shirley I. MIEKKA et al.FILING DATE
August 31, 2001GROUP
2881**U.S. PATENT DOCUMENTS**

*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
	A1	4,336,247	06/1982	Eriksen			
	A2	4,931,361	06/1990	Baldeschwieler et al.			
	A3	5,012,503	04/1991	Nambu et al.			
	A4	5,044,091	09/1991	Ueda et al.			
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	A7	6,060,233	05/2000	Wiggins			
	A8	6,258,821	07/2001	Stogniew et al.			
	A9						
	A10						
	A11						
	A12						

U.S. PATENT APPLICATION PUBLICATIONS

*EXAMINER'S INITIALS	CITE NO.	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS	FILING DATE
	B1						

U.S. PATENT APPLICATIONS

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	C1						

FOREIGN PATENT DOCUMENTS

*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*DATE	*COUNTRY	CLASS	SUBCLASS	Translation
							Yes No
	D1						
	D2						
	D3						
	D4						
	D5						

OTHER ART

*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)
	E1	Alper, T. et al., Protection by Anoxia of the Scrapie Agent and some DNA and RNA Viruses Irradiated as Dry Preparations, J. Gen. Virol., 3:157-166 (1968)
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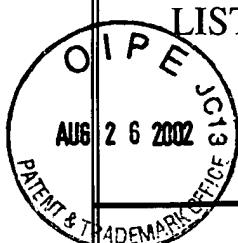
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	E4	Blanchy, B.B. et al., Immobilization of Factor VIII on Collagen Membranes, <i>J. Biomedical Materials Research</i> , 20:469-479 (1986) (John Wiley & Sons, Inc.)
	E5	Borisova, E.A. et al., Protein Degradation During Interphase Death of Thymocytes Induced by Radiation and Dexamethasone, pp.519-521 (1990)
	E6	Boyer, T.D. et al., Radiation Inactivation of Microsomal Glutathione S-Transferase, <i>The Journal of Biological Chemistry</i> , 261:16963-16968 (1986)
	E7	Chanderkar, L.P. et al., The Involvement of Aromatic Amino Acids in Biological Activity of Bovine Fibrinogen as Assessed by Gamma-Irradiation, <i>Radiation Research</i> , 65:283-291 (1976) (Academic Press, Inc.)
	E8	Chanderkar, L.P. et al., Radiation-Induced Changes In Purified Prothrombin and Thrombin, <i>Biochimica et Biophysica Acta</i> , 706:1-8 (1982) (Elsevier Biomedical Press)
	E9	Chin, S. et al., Virucidal Treatment of Blood Protein Products With UVC Radiation, <i>Photochemistry and Photobiology</i> , 65:432-435 (1997) (American Society for Photobiology)
	E10	Dyskin, E.A. et al., Hemomicrocirculatory Bed in the Wall of Hollow Organs of the Dog Gastrointestinal Tract at Portal Hypertension, <i>Arkh Anat Gistol Embiol</i> , 93:58-68 (1987)
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	E12	Hsiue, G. et al., Absorbable Sandwich-Like Membrane for Retinal-Sheet Transplantation, pp.20-25 (2002) (Wiley Periodicals, Inc)
	E13	Jensen, J. et al., Membrane-bound Na, K-ATPase: Target Size and Radiation Inactivation Size of Some of Its Enzymatic Reactions, <i>J. Biological Chemistry</i> , 263:18063-18070 (1988) (Am. Soc. for Biochem. and Mol. Biol.)
	E14	Kamat, H.N. et al., Correlation of Structural Alterations in Bovine Fibrinogen with Loss of Clotting Properties After Gamma Irradiation, <i>Radiation Research</i> , 49:381-389 (1972) (Academic Press, Inc.)
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	E18	Le Maire, M. et al., Effects of Ionizing Radiations on Proteins, <i>Journal of Biochem.</i> , 267:431-439 (1990)
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	E20	Marx, G. Protecting Fibrinogen with Rutin During UVC Irradiation for Viral Inactivation, <i>Photochemistry and Photobiology</i> , 63:541-546 (1996) (American Society for Photobiology)
	E21	Nagrani, S. et al., The Radiation-Induced Inactivation of External Yeast Invertase in Dilute Aqueous Solution, <i>Int. J. Radiat. Biol.</i> , 55:191-200 (1989) (Taylor & Francis Ltd.)

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		APPLICANT Shirley I. MIEKKA et al.
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*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)
	E22	Nielsen, M. et al., The Apparent Target Size of Rat Brain Benzodiazepine Receptor, Acetylcholinesterase, and Pyruvate Kinase Is Highly Influenced by Experimental Conditions, The Journal of Biological Chemistry, 263:11900-11906 (1988) (The American Society for Biochemistry and Molecular Biology, Inc.)
	E23	Plavsic, Z. M. et al., Resistance of Porcine Circovirus to Gamma Irradiation, BioPharm, pp. 32-36 (April 2001)
	E24	Potier, M. et al., Radiation Inactivation of Proteins: Temperature-Dependent Inter-Protomeric Energy Transfer in Ox Liver Catalase, Biochem. J., 298:571-574 (1994)
	E25	Sakai, T. et al., Microbiological Studies on Drugs and Their Raw Materials. IV. Sterilization of Microbial Contaminants in Enzyme Powder by Gamma Irradiation, Chem. Pharm. Bull., 26:1130-1134 (1978)
	E26	Salim-Hanna, M. et al., Free Radical Scavenging Activity Of Carnosine, Free Rad. Res. Comms., 14:263-270 (1991) (Harwood Academic Publishers GmbH)
	E27	Song, K.B. et al., Effect of Gamma-irradiation on the Physicochemical Properties of Blood Plasma Proteins, 2002 Annual Meeting and Food Expo-Anaheim, California, Session 30C-1, Food and Chemistry: Proteins, (June 2002) (Abstract)
	E28	Suomela, H., Inactivation of Viruses in Blood and Plasma Products, Transfusion Medicine Reviews, 7:42-57 (1993) (W.B. Saunders Company)
	E29	(Abstract of EP0919198A2 and EP0919198A3 (Delphion-DERABS Abstract #G1999-304614))
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	E31	Website: www.usacc.org/attaccc/ppt.html , (Advanced Technology Applications for Combat Casualty Care, 2001 Presentations, US Army Medical Research and Material Command Combat Casualty Care Research Program (2001))
	E32	Website: www.usacc.org/RevisedStepB.html , Bakaltcheva, I. et al., (FY01 Request for Proposals-Intramural-Revised 2, Combat Casualty Care Research Program, (2000))
	E33	Website: www.benvue.com/history/history_content.html , (2002)
	E34	Website: www.phase-technologies.com/html/vol.2no1.html , Jennings, T.A., (Glossary of Terms for Lyophilization) (1999)
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	E37	Website: www.phase-technologies.com/html/vol.2no2.html , Jennings, T.A., (What I Wish I Knew About Lyophilization) (1999)
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